K133824

MAR 1 4 2014

Section 5 – 510(k) Summary

GC AMERICA INC.
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1. Submitter Information:

GC AMERICA INC.
3737 W. 127th Street
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Contact Person: Mark Heiss, D.D.S.
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Date Prepared: December 12, 2013

2. Device Name:

Proprietary Name: CERASMART
Classification Name: Tooth shade resin material
Device Classification: Class II, 872.3690
Product Code: EBF

3. Predicate Devices:

Company	Device	510(k) No.	Date Cleared
3M ESPE Dental Products	LAVA Ultimate	K110131	1/21/2011
GC America Inc.	MFP-051	K123631	7/23/2013
GC America Inc.	GRADIA CORE	K082171	10/30/2008

4. Description of Device:

CERASMART is a pre-cured composite block for milling CAD/CAM indirect restorations. The milled device is used for the restorations of both anterior and posterior teeth.

5. Indications for Use:

The product is indicated for inlays, onlays, veneers and full crown restorations, including crowns on implants.

6. Technological characteristics:

All the components of the applicant device, CERASMART, have already been used in two of the predicate devices (MFP-051 and GRADIA CORE).

7. Substantial equivalence:

Thus, the new and predicate devices are the same in function, and similar in composition and intended use. This supports that the compatibility and safety of the applicant device are substantially equivalent to the predicate devices.

Differences:

Compared to 3M Lava Ultimate, Cerasmart has a lower water sorption using ISO 10477.
MFP-051 and Gradia Core are not pre-cured. MFP-051 is light cured and Gradia Core is chemical cured.

8. Performance Testing – Bench:
   Flexural strength/MPa
   Water Sorption/$\mu g/mm^3$
   Solubility/ $\mu g/mm^3$
   Radiopacity

PACKAGE

1. 3 sizes: 12/ 14/ 14L
2. 5 blocks in one package
3. Available CAD/CAM system: Aadva/ CEREC /E4D

SHADE

33 shades
(A1 HT, A2 HT, A3 HT, A3.5 HT, A4 HT, B1 HT, B2 HT, B3 HT, B4 HT, C1 HT, C2 HT, C3 HT, C4 HT, D2 HT, D3 HT, D4 HT, A1 LT, A2 LT, A3 LT, A3.5 LT, A4 LT, B1 LT, B2 LT, B3 LT, B4 LT, C1 LT, C2 LT, C3 LT, C4 LT, D2 LT, D3 LT, D4 LT, BL)

Shelf Life: 5 years from date of manufacture

	Applicant device	**Comparative device**		
Product category	CAD/CAM restorative	CAD/CAM restorative	Light-cured radiopaque universal composite restorative	Light-cured radiopaque universal composite restorative
Trade name	CERASMART	LAVA Ultimate (K110131)	MFP-051 (K123631)	GRADIA CORE (K082171)
Manufacturer	GC Corporation	3M ESPE	GC Corporation	GC Corporation
Intended use	inlays, onlays, veneers and full crown restorations, including crowns on implants.	inlays, onlays, veneers and full crown restorations, including crowns on implants.	1. Direct restorative for class 1, 2, 3, 4 cavities. 2. Direct restorative for wedge-shaped defects and root surface cavities. 3. Direct restorative for veneers and diastema closure.	1. Core build-up. 2. Post cementation.
Product description	CERASMART is a pre-cured composite block for milling CAD/CAM indirect restorations. The milled device is used for the restorations of both anterior and posterior teeth.	The product is a strong, wear-resistant and highly esthetic mill block that provides a fast and easy-to-use alternative to porcelain blocks for milling CAD/CAM indirect restorations. The material is specially processed to enhance its properties for use in CAD/CAM milling procedures.	MFP-051 is a light cured nano-filled radiopaque composite resin filled in a syringe and unitip. The device is used for the restorations of both anterior and posterior teeth.	GRADIA CORE cartridge is a two-paste (base and catalyst) type, dual-cure composite resin filled in double syringe to provide auto-mixing system. The device is used as composite resin for restoration, post cementation and core build-up.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 14, 2014

GC America, Inc.
Mark Heiss, DDS
Director – Academic & Regulatory Affairs and Professional Relations
3737 West 127th Street
Alsip, IL 60803

Re: K133824
Trade/Device Name: CERASMART
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Codes: EBF, EBG
Dated: December 12, 2013
Received: December 17, 2013

Dear Dr. Heiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 – Indications for Use Statement

Indications for Use

510(k) Number (if known): K133824

Device Name: CERASMART

Indications for Use:

The product is indicated for inlays, onlays, veneers and full crown restorations, including crowns on implants.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
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